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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,751	08/07/2000	BERTIL R.R. PERSSON	U012883-2	9637

7590

12/04/2002

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,751

Applicant(s)

PERSSON ET AL. *al*

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Election/ Restriction Requirement filed 9/23/02

1. Claim 12 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6. The elected claims are 1-11 and 13-19.

Claims 1-11 and 13-19 are pending in this application. Of these claims, claims 1 and 19 are independent.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically in claim 1, "the apparatus is disposed, on treatment of tissue or organs, adjacent or in said region" amounts to inferential recitation of the body, which renders these claim non-statutory. A phrase such as -- the apparatus is adapted to be disposed, on treatment of tissue or organs, adjacent or in said region-- is suggested to address the understood intent of the applicant and avoid the 35 U.S.C. 101 rejection. Appropriate correction is required.

Drawings

3. The drawings, figures 1, 2, 3, 4a-b, 5, 6b, 7 a-b and 10 are objected to under 37 CFR 1.83(a) because the rectangular boxes are not labeled as described in the specification and because and the impedance unit (50) of claims 1 and 19, the sensors (14) of claim 8 and the layer of porous material (27) of claim 18 can not be found in the drawings. Any structural detail that

is essential for a proper understanding of the disclosed invention should be shown in the drawings. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The first paragraph of the specification needs to be changed as there are two independent claims.
5. The specification is objected to because section headings are missing.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.

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- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and

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problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the

World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Objections

6. The claims section must begin with the phrase "We claim:" or "What is claimed is:" or a comparable phrase. Appropriate correction is required.
7. The reference numerals in the claims are superfluous and should be deleted. Appropriate correction is required.
8. In claim 1, line 12 it appears "organs adjacent" should be --organs, adjacent--.
9. Claim 19 is objected to because it appears "Apparatus" should be --An apparatus--, "adopted" should be --adapted-- and in line 5, "voltage pulses said" should be --voltage pulses, said--.

Abstract

10. The Examiner is unable to locate the Abstract in the specification. An Abstract is required, hence correction is required.

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language

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should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The placement of "characterized" in claim 1 is questioned as the voltage generator, the electrodes and the means of distributing the voltage pulses are not positively claimed. For purposes of this response, positive recitation by the Applicant of the noted elements is assumed.

Claim 1 is indefinite because it is unclear if the electrodes are included in the apparatus or if the electrodes are connected to the apparatus (lines 3-5).

Claim 1 is indefinite because it is unclear if the electrodes are secured at the region or inserted in the region (lines 7-9). Based on the Applicant's election, the electrodes are read to be inserted in the region.

In claim 1, line 13, "the impedance" lacks antecedent basis.

Claim 1 is indefinite because in lines 14-15 it is unclear if the unit is included in the apparatus or connected to the apparatus.

In claim 1, lines 16-17, "the measurement impedance and/or resistance" lacks antecedent

basis.

In claim 1, line 17, "the size" lacks antecedent basis.

In claim 1, line 18, "the voltages" lacks antecedent basis.

In claim 2, the term VDU needs to be clarified.

In claim 2, lines 4-5, it appears "a pulse or chain of pulses" should be --the pulse or chain of pulses--.

In claim 2, line 5, "the form" lacks antecedent basis.

In claim 2, line 8, "said calculated formation" lacks antecedent basis.

In claim 3, lines 3-4, "said means for emitting voltage pulses" lacks antecedent basis.

Claim 3 is indefinite because it is unclear if the electrodes are common for the impedance measurement unit and the means for emitting voltage pulses or if separate electrodes are provided for the measurement unit and the means for emitting voltage pulses.

In claim 4 it appears "a restriction region" should be --the restricted region--.

Claim 4 is indefinite because it is unclear if the electrodes are positioned relative to electrical fields passing through a region or if the electrodes are placed in the region. Based on the Applicant's election, the electrodes are read to be placed (by insertion) in the region.

Claim 5 is indefinite because it is unclear if the means supplies a substance, a material and/ or a radiation. Also, the final phrase of the claim "or that the apparatus is designed to cooperate with such a means" is awkward and unclear.

In claim 6, line 3, the appears "detecting electrical fields" should be --detecting the

electrical fields--.

Claims 6 and 8 are inconsistent relative to claims 1 and 2 because it appears “the control and converter unit” of claims 1 and 2 has become “the registration and converter device” in claims 6 and 8. The confusion stems from both elements having the same reference numeral. For this action, the “unit” and “device” are read as the same element.

In claim 6, lines 5-6 and 7-9, “the size”, “the electrical field strength”, “the treatment region”, “the amplitude” and “the high voltage generator” lack antecedent basis.

In claim 6 “the size of the electrical field strength” is unclear.

In claim 6, lines 7-10, it is unclear if the device is connected:

to the generator, or

to the means connected in between the generator and the electrodes, or

to both the generator and the means connected in between the generator and the electrodes.

In claim 8 it appears “sensors” should be noted as --second sensors-- to avoid confusion with claim 6.

In claim 8, line 3, “the distance” lacks antecedent basis.

Claim 10 is indefinite because it is unclear how much of the electrodes are covered by insulation.

In claim 11 it is unclear if the electrodes are placed on or in the treatment region. Based on the Applicant’s election, the electrodes are read to be placed in the region.

In claim 14, “the fixture” lacks antecedent basis.

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Claim 15 is indefinite because it is unclear if the electrodes are place on the applicator surface or if the electrodes are placed in channels to be inserted into the tissue around the applicator. Based on the Applicant's election, this claim is read as being inserted in the tissue.

In claim 16 it appear "each one disposed" should be --each one of the at least one cannula disposed--.

Claim 17 is indefinite because it is unclear if the electrodes consist of radioactive material or if apertures in the electrodes contain radioactive preparations.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 1, 3-7, 9-11, 13-16, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6141582) in view of Hofmann (US 6208893). Mori et al. discloses an iontophoresis system and its control process of current.

As to claim 1, the apparatus for controlling the electric fields comprises an output circuit member (6), read as the voltage generator, that provides voltage pulses to the donor device and the reference device and their associated electrodes (42) to focus the voltage on the restricted region, read as the treatment region. The voltage control member (4), read as the means for distributing the voltage pulses, controls the distribution of the voltage in treatment region. The current detection member (8) and the voltage conversion circuit member (9) perform the function of the impedance measurement unit, that enables the voltage control member (4) to control the voltages, including the amplitude, based impedance measurements so an optimal electrical field is applied to the electrodes and ultimately to the treatment area (abstract; figures 1, 13 and 14; c 2, ll 62-65; c 4, l 66 – c 5, l 14; c 7, ll 38-41; c 11, ll 26-67; c 12, 22-33).

The donor device can be an unpolarized electrode (c 7, ll 63-67).

As to claim 2, a display member, read as the VDU (screen) shows the configuration of the waveform selected by the control unit on the screen (figure 1; c 13, ll 4-9).

As to claim 3, the electrodes are common to the control unit and the means for emitting voltage pulses (figure 1).

As to claim 4, the electrodes are positioned such that the electrical field passes through the restricted region (abstract and c 1, ll 15-26).

As to claim 5, the means for supplying therapeutic substances, genetic material or radiation to the restricted region is shown as drug iontophoresis means (c 2, l 60 – c 3, l 9).

As to claim 6, the current detection units (A1-A5), read as the sensors, detect the electrical fields formed by the electrodes, and provide feedback to the control unit to enable an optimum electrical field to be created by adjusting the source of the electrical fields and the amplitude of the pulses (figure 2; c 4, l 66 – c 5, l 14; c 7, ll 1-5; c 12, ll 52-67).

As to claim 18, the electrodes are coated with a porous material to accommodate therapeutic substances (figure 14; c 2, l 60 – c 3, l 9; c 8, ll 10-16).

As to claim 19, the apparatus for treating tumors comprises a donor device and a reference device and their associated electrodes (42) to focus the voltage on the treatment region. The voltage is supplied by an output circuit member (6). The current detection member (8) and the voltage conversion circuit member (9) perform the function of the impedance measurement unit, that enables the voltage control member (4) to control the voltages of each treatment based impedance measurements so an optimal electrical field is applied to the electrodes and ultimately to the treatment area. Anti-malignancy drugs can be applied by the system, hence treating tumors in inherent. (abstract; figures 1, 13 and 14; c 2, ll 62-65; c 9, ll 43-66; c 11, ll 26-67).

Mori et al. disclose the claimed invention expect for:

- the electrodes being alternately excited and only two at a time (claim 7),
- the electrodes being needles (claim 9),
- the electrodes being insulated (claim 10),
- the electrode applicator temporarily fixing the electrodes prior to placement (claim 11),
- the fixture fixing the electrodes in a set pattern. (claim 13),

- providing holes in the fixture enabling the desired treatment pattern to be established (claim 14),
- the electrodes being placed in channels discharged in apertures in the applicator and the electrodes being controlled remotely (claim 15) and
- the cannula enclosing the electrode (claim 16).

Hofmann discloses an electroporation apparatus with connective electrode template for use with interstitial tumors (c 1, l 66 – c 2, l 9) and teaches that it is known to:

- alternately excite the electrodes and only two at a time (claim 7),
- provide electrodes that are needles (claim 9),
- insulate the electrodes (claim 10),
- temporarily fix the electrodes prior to placement (claim 11),
- fix the electrodes in a set pattern using a fixture (claim 13),
- provide holes in the fixture enabling the desired treatment pattern to be established (claim 14),
- place the electrodes in channels discharged in apertures in the applicator and control the electrodes remotely (claim 15) and
- use a cannula to enclose the electrode (claim 16).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the iontophoresis system and its control process of current as taught by Mori et al., with the following elements as taught by Hofmann:

- electrodes being alternately excited and only two at a time (claim 7) to provide an electrical field that optimizes delivery of the drugs (c 11, ll 30-34 and c 13, ll 46-53),

- electrodes being needles (claim 9) to enable electrode placement in the tissue near the tumor (c 4, ll 42-49),
- electrodes being insulated (claim 10) to enable targeted stimulation (c 10, ll 1-4),
- a connector template (22), read as the electrode applicator, temporarily fixing the electrodes prior to placement (claim 11) to enable a treatment pattern to be defined (c 8, ll 45-54),
- faces (24), read as the fixture, fixing the electrodes in a set pattern (claim 13) to enable the electrodes to be targeted in the tissue (c 9, ll 8-15),
- holes provided in the fixture to enable the desired treatment pattern to be established (claim 14) (figure 1),
- electrodes discharged in openings, read as the apertures, in the channels (120) formed by the frame (114) and the circuit boards of the applicator (claim 15) to secure the electrodes in position (figure 11 and c 10, ll 53-56), these electrodes being controlled remotely to enable the clinician freedom to monitor and care for the patient (c 7, ll 46-58), and
- a socket (26), read as the cannula, enclosing the electrode (claim 16) to provide a guide, with conductive contact, for the electrodes (c 10, ll 56-67).

14. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6141582) in view of Hofmann (US 6208893) and further in view of Gough et al. (US 5928229). As discussed in paragraph 13 of this action, modified Mori et al. disclose the claimed invention except for a means in the control unit to manually or automatically accept the waveform.

Gough et al. disclose a stimulation apparatus for treating a tumor and teach that it is known to provide a means in the control unit to manually (c 9, ll 38-39) or automatically (c 9, ll 47-50) accept the waveform (c 9, ll 2-16 and 31-50) to enable alternate control mechanisms.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified iontophoresis system and its control process of current as taught by modified Mori et al. with the manual and automatic waveform control unit as taught by Gough et al. to provide system flexibility so the operator can manually vary the stimulation to identify the optimum therapy and then can automatically provide stimulation of the defined therapy using a programmed stimulation profile enabling the operator freedom to provide additional monitoring and care for the patient during the therapy session.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6141582) in view of Hofmann (US 6208893) and further in view of Eggers et al. (US 5928159). As discussed in paragraph 13 of this action, modified Mori et al. disclose the claimed invention except for sensors detecting the distance between electrodes and the control unit adjusting the electrode voltage based on the distance.

Eggers et al. disclose an apparatus for characterizing and treating tumors and teach that it is known to use sensors to detect the distance between electrodes and to enable the control unit to adjust the electrode voltage based on the distance (c 6, ll 20-64). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified iontophoresis system and its control process of current as taught by modified Mori et al., with the sensors to measure distance between the electrodes and to enable the control unit to provide therapy based on the distance measurements as taught by Eggers to enable interstitial

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tumors to be more accurately monitored so the treatment parameters can be optimally varied to provided effective treatment for the tumor (c 5, ll 25-36).

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6141582) in view of Hofmann (US 6208893) and further in view of Mawad (US 6428462). As discussed in paragraph 13 of this action, modified Mori et al. disclose the claimed invention except for the electrode consisting of radioactive material.

Mawad discloses a radiotherapy implant and teaches that it is known to use an electrode with a radioactive device to enable placement of radiation near the tumor (c 3, ll 34-37 and c 5, ll 21-49). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the iontophoresis system and its control process of current as taught by modified Mori et al., with the radioactive therapy implant as taught by Mawad to provide radiotherapy for a patient where combined chemotherapy and radiation therapy is the recommended treatment (c 1, ll 20-25).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

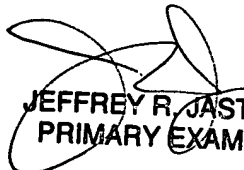
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

11/29/02


JEFFREY R. JASTRZAB
PRIMARY EXAMINER

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